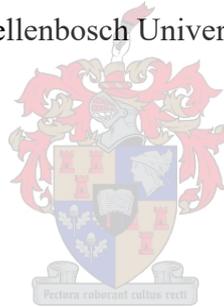


# **A profile of surgical complications in gynaecology at a teaching hospital in South Africa**

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Presented in fulfilment of the requirements for the degree of  
Master of Medicine (MMed)  
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**December 2022**

## **Declaration**

I, the undersigned, hereby declare that the work contained in this assignment is my original work and that I have not previously submitted it, in its entirety or in part, at any university for a degree.

Signed: T. Gallant

Date: 26 August 2022

## **Acknowledgements**

First and foremost, I would like to thank my Creator for granting me good health and the means to complete this study. Secondly, to my loving husband, Moegamad and daughter, Hanaan, thank you for all the support and sacrifices you have made with and for me. To my parents, siblings and friends, thank you for your continued support and encouragement. To my supervisor, Dr Haynes van der Merwe, thank you for your commitment, support, and valuable guidance. Lastly, thank you Dr Moxley for your continued guidance and support.

## Definitions

### Blood stream infection

- a. “An infection that cannot be attributed to another infection and meets the following criteria:
- b. Patient has a recognised pathogen cultured from blood culture that is not related to an infection at another site.
- c. Patient has at least one of the following signs or symptoms: fever (>38 degrees Celsius), chills or hypotension and has at least one of the following:
  - i. Common skin contaminant cultured from two or more blood cultures drawn on separate occasions.
  - ii. Common skin contaminant cultured from at least one blood culture from a patient with an intravascular line, and a physician starts antimicrobial therapy.
  - iii. Positive blood antigen test.”

### Bowel injury

“Thermal or sharp injury of the bowel.”

### Deep vein thrombosis (DVT)

“New clot or thrombus in the venous system.”

### Paralytic ileus

“Failure to tolerate food or defecate for three or more days after surgery.”

### Pneumonia

“Chest radiograph changes with new or progressive and persistent infiltrates, consolidation or cavitation, and at least one of the following:

- a. Fever (> 38 degrees Celsius) and no other cause found
- b. Leucopaenia(white cells < 4000/mm<sup>3</sup>) or leucocytosis(white cells > 12000/mm<sup>3</sup>)
- c. Patients more than 70 years old with altered mental state and no other cause found

And at least 2 of the following:

- a. New onset purulent sputum or change in character of sputum, increased secretions or increased suctioning requirements
- b. New onset worsening cough, or dyspnoea, or tachypnoea
- c. Rales or bronchial breathing

- d. Worsening gas exchange (hypoxaemia, increased oxygen requirements or increased ventilator demand)”

### **Post-operative haemorrhage**

“Blood loss in the first 72 hours after surgery requiring a blood transfusion”

### **Pulmonary embolism**

“A new blood clot or thrombus in the pulmonary arterial system as diagnosed by the appropriate diagnostic tests including CT angiography or scintigraphy.”

### **Surgical complications**

Surgical complications are defined using the definitions from the ‘European Perioperative Clinical Outcome definitions: a statement from ESA-ESICM joint taskforce on perioperative outcome measures’.(1)

### **Surgical site sepsis**

#### *a. Superficial*

“Infection involving only the superficial surgical incision which meets the following criteria:

- i. Infection occurring within the first 30 days
- ii. Involving only the skin and subcutaneous tissue
- iii. The patient has at least one of the following:
  - Purulent drainage from the superficial incision
  - Organism isolated on an aseptically obtained culture of fluid or tissue from the superficial incision and at least one of the following: pain or tenderness, localized swelling, redness, heat, or superficial incision purposefully opened by the surgeon and is culture positive or not cultured.
  - Diagnosis of infection by the surgeon or attending physician.”

#### *b. Deep*

“An infection which involves both superficial and deep parts of surgical incision and meets the following criteria:

- i. Infection occurring within 30 days after surgery if no surgical implant is left in place or within one year if an implant is left in place.
- ii. The infection appears to be related to the surgical procedure and involves the deep tissues of the incision

iii. The patient has at least one of the following:

- Purulent drainage from the deep incision but not from the organ or space of the surgical site.
- Deep incision spontaneously dehisces or is deliberately opened by the surgeon and is culture positive or no cultures taken whilst the patient has: fever, localised pain or tenderness.
- Abscess formation or evidence of infection involving the deep incision found on direct examination, during surgery or on histopathologic or radiologic examination.
- Diagnosis of deep infection diagnosed by surgeon or attending physician.”

c. *Organ space or compartment sepsis*

i. “Organ space or compartment sepsis Infection of any body part excluding skin, fascia and muscle layer with the following:

- Infection must commence within 30 days of the procedure
- Sepsis appears to be due to surgery
- It should have:
  - Purulent discharge draining from a drain through a stab wound or surgical site
  - Abscess formation identified clinically, histologically or radiologically
  - Organism identified on culture of fluid in space or compartment collected aseptically
  - Infection deemed so by attending surgeon or physician”

### **Urinary tract infection**

“Positive urine culture of more than  $10^5$  colony forming units per millilitre of less than 2 microorganisms with at least one of the following: fever, urgency, frequency, dysuria, suprapubic tenderness, and renal angle tenderness without any other cause found.”

### **Urinary tract injury**

“Injury to kidney, bladder, ureter and urethra.”

## Abbreviations

95% CI	95% confidence interval
ASA	American Society of Anaesthesiologist
ASOS	African surgical outcome study
BMI	Body mass index
CD4	Cluster of differentiation 4
CI	Confidence interval
CDC	Centre for Disease Control
COPD	Chronic airway obstructive disease
DVT	Deep vein thrombosis
ECM	Electronic content management
EUA	Examination under anaesthesia
FDP	Freeze dried plasma
FFP	Fresh frozen plasma
GEK	Gynaecology Evaluation Clinic
HAART	Highly active antiretroviral treatment
Hb	Haemoglobin
HIV	Human immunodeficiency virus
ICU	Intensive care unit
I&D	Incision and drainage
ISOS	International Surgical Outcome Study
Kg	Kilogram
LMIC	Low- and middle-income countries
LN	Lymph node
MINS	Myocardial injury after non-cardiac surgery
n	Number
NS	Not significant
OR	Odds ratio
PID	Pelvic inflammatory disease
SASOS	South African Surgical Outcomes Study
SD	Standard deviation
RR	Risk ratio
TAH	Total abdominal hysterectomy
TBH	Tygerberg Hospital
TIA	Transient ischaemic attack
TVT	Transvaginal tape
UTI	Urinary tract infection

USA United States of America  
WHO World Health Organization

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## Extended background

It is estimated that world-wide, over three hundred million patients have surgical procedures per year. Most surgical procedures are performed in high-income countries, and the reported post-operative complication rate is close 20% (2) A vast majority of patients do not have access to health care, and if surgery is performed, they often have suboptimal care and surveillance for complications. Unfortunately, postoperative complications not only increase costs but also affect quality of life.

Gynaecological surgical procedures are performed in large numbers across the world daily for a myriad of reasons. The most common gynaecological procedure is the hysterectomy. Despite being readily performed with much emphasis placed on good surgical technique, it is not without morbidity.

Before considering surgical complications relevant to gynaecological surgery alone, it is important to understand the context of surgical complications locally and internationally. The International Surgical Outcome Study (ISOS) looked at low, middle, and high-income countries and compared the surgical outcomes and mortality rates (2) This cohort study involved 44814 participants and assessed postoperative in-hospital outcomes and mortality rate after elective surgical procedures. Post-operative complications occurred in 16.8% of patients, and a mortality rate of 2.8% was reported. Middle- and low-income countries had a higher mortality rate compared to high-income countries, but there was no statistical significant difference in the post-operative complication rates reported. The study had 5674 patients requiring gynaecological surgery with a complication rate of 9.8% and 0.1% mortality rate within that cohort (2)

The findings of ISOS became a strong motivator for the South African Surgical Outcome Study (SASOS). This study assessed the mortality rate of non-cardiac surgery in participants older than 16 and the need for planned and unplanned critical care admissions. The cohort consisted of 3927 patients. The overall mortality rate was 3.1%. Critical care admissions were required for 6.4% of patients. Gynaecological surgical procedures accounted for 13.4% of the study population and in this cohort, the admission rate to a critical care units occurred in 4% of patients. Surprisingly, the larger proportion of patients had unplanned admissions to critical care units (3) The study highlighted the need to improve primary care and surveillance to detect and treat complications. Furthermore, the referral system should be improved because access

to emergency surgery and critical care facilities is likely to decrease deaths related to surgery (3)

The investigators of SASOS later conducted the African Surgical Outcome Study (ASOS), which represented a landmark trial assessing patient perioperative outcomes and mortality rate in Africa. The ASOS was a 7-day prospective cohort study and 11422 patients were recruited. The caesarean section was most commonly performed surgery, and overall complication and mortality rates were 18.2% and 2.1%, respectively. Despite similar complication rates to ISOS, the mortality rate was much higher, and the most common cause of death was infection. Gynaecologic surgery accounted for 11.5% of the cohort, and the complication rate was 7.7%, with a mortality rate of 2.9%. This study showed that there is a dire need for surgical expertise and surveillance in low- and middle-income countries (4)

The data regarding complications associated with specific gynaecological procedures is limited. Hysterectomies are one of the most commonly performed surgical procedures in the developed world. This procedure is commonly associated with complications, such as bleeding, infection, urinary tract injury, bowel injury, and thromboembolism. An Australian study, conducted over 23 years, assessed the outcomes of hysterectomies for benign indications. Results indicated that 8.7% of these women had complications, with the most common being haemorrhage or transfusion without preceding anaemia, followed by urinary tract complications, including injury and urinary tract infection. This study also showed that women with post-procedural complications had a 2.8 day longer stay(5).

Ellessawy et al investigated a risk assigned score and the correlation with complications in hysterectomies. The scores were based on factors like previous surgery. The study showed a proportionate relationship with higher scores correlated with a higher chance of complications(6). The positive association between higher risk assigned scores and the probability of complications, demonstrates the importance of risk stratification and may improve surgery planning.

With technological advances and the demand for less invasive surgical methods with shorter hospital stays, laparoscopic surgery has increased. Initially, the data on complications associated with laparoscopic surgery was limited. Later, between 1992 and 1998, a prospective observational study was conducted to ascertain the incidence of laparoscopic complications. A total of 1033 patients were included, and over 80% underwent advanced laparoscopic

procedures. The overall incidence of complications was 3%, with the majority of the complications occurring during the insertion of the trocars, more commonly the secondary one. Vessel injury and haemorrhage remained the most common complications, accounting for almost half of the complications recorded. Urinary tract and bowel injuries occurred less commonly, with complication rates of 12.9 and 6.4%, respectively. There was consensus that complication rates at laparoscopic surgery was on the rise (7).

Patients with a gynaecological malignancies are at increased risks for complications, including thromboembolic events, urinary tract complications including fistula formation, bowel injury, haemorrhage, and requiring a blood transfusion(8).

Individual complications are reported in a few studies. Haemorrhage is one of the three most common complications. Surgeons are trained to perform surgery with meticulous attention to haemostasis, as there are well-known associations with major blood loss and transfusions (9,10). In a study investigating the 30-day mortality and the non-fatal outcomes of a massive blood transfusion, the 30-day mortality in those who received a massive blood transfusion was 17%, and over 50% of patients had non-fatal complications(11). A study conducted in Michigan, USA, showed that a blood loss of more than 400mls during a hysterectomy was associated with a 2.5 fold increase in the risk of complications. These patients also had a higher re-admission rate (3.6%), a reoperation rate of 2.1%, the need for blood transfusion in 2% of patients, and 4.9% experienced a hospital stay of longer than four days(12). The implication of this on the health care system and patient quality of life is significant.

Urinary tract complications are commonly reported in the literature. These include bladder injuries, ureteric injuries, fistula formation, and urinary tract infections. The close anatomical relationship between the urinary tract system and the female reproductive system is highlighted in gynaecologic surgical procedures. The overall incidence of urinary tract injury is about 1%. It is estimated that 82% of ureteric injuries occur during pelvic surgery and 75% of urinary tract injuries are associated with gynaecologic surgical procedures(13). Bladder injury was the most common urinary tract injury with an incidence of 0.8%, whereas ureteric injury incidence is about 0.3%(14) Urinary tract infection could lead to increased pain and decreased mobility, with vesico-vaginal fistulae being one of the most debilitating complications, often with delayed and difficult repair, leading to poor quality of life.

Bowel injuries range from serosa tears to complete transections and occurs in both open and laparoscopic surgery. The incidence for both surgical approaches ranges between 0.3% and 0.54% with injury commonly occurring in open surgery when there are dense adhesions(15). In contrast, laparoscopic injury commonly occurs during the manipulation of the bowel or through thermal injury. Thermal injury usually goes unnoticed during surgery and has a delayed presentation 72 to 96 hours later(16)

When comparing the rates of surgical site sepsis in gastro-intestinal surgery in low-, middle- and high income countries, the literature shows that the incidence of surgical site sepsis is much higher in low- and middle- income countries, despite the vast majority of surgery occurring in high-income countries (17). Diabetes has been shown to have a significant association with surgical site sepsis (17) This risk is amplified when there is poor post-operative glucose control. Additionally, in a small study done by Zhang et al, HIV, particularly those with a low CD4 count, was significantly associated with surgical site sepsis (18)In gynaecologic surgical procedures, the incidence of surgical site sepsis is about 2%. Gynaecologic surgical procedures are classified as clean-contaminated surgery, due to the polymicrobial microbiome of the vagina and its communication with the uterus via the cervical os(19). Other risk factors, including an increased body mass index (BMI) and a poor resource setting, predispose this cohort to wound sepsis. An American study suggested that a raised BMI was associated with more wound complications like wound sepsis and dehiscence (20) The South African study by Butt et al demonstrated similar findings in support of a positive correlation between BMI and wound sepsis (21)

Multiple risk factors predispose to the development of thromboembolic events. Prophylaxis is important as 75% of deep vein thrombi develop intra-operatively and the other 25% develop within 72 hours of surgery (16). It is still one of the leading causes of mortality in the developed world, with a mortality rate of about 8-30% if left undiagnosed (22). Surgical procedures for benign conditions have an approximate incidence of venous thromboembolism of 0-2% (23) The incidence of thromboembolic events is higher in patients with malignancy, and in patients older than sixty years old or those have prolonged surgery (23) In the South African context, diagnosis and treatment of thromboembolic events bear a large health burden. Affordable anticoagulation require intense monitoring and follow-up. This places a burden on lab services, health care facilities and many patients are lost to follow-up. On the contrary, anticoagulation not requiring such intense surveillance is inaccessible to the majority of the population due to

its high cost. It is thus important to identify those at risk and ensure the appropriate preventative measures are in place.

Lastly, it would be assumed that surgeries performed by people of varying skill may influence the complication. This assumption was disproven by the VALUE study where the outcomes for both specialists and non-specialists were similar(24)Despite specialists being allocated more complex surgery, they are often supervising the non-specialist group or are called to assist when complications arise.

For safe service delivery, it is important to be aware of complication rates and the associated risk factors. With this known, one would be able to adequately triage surgical cases, allocate the appropriate level of surgical skill to a case or ensure that adequate supervision is present and identify gaps in knowledge and training. Complications are inevitable but having the above information may assist in mitigating risk and subsequently decrease complication associated costs and disease burden.

## **Publication-ready manuscript**

The following manuscript has been prepared for submission to The South African Journal of Obstetrics and Gynaecology. The journal's aims and scope, as well as author guidelines are given in Appendix A.

# **A profile of surgical complications in gynaecology at a teaching hospital in South Africa**

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## **Abstract**

### **Background and Aim**

Information about current gynaecological surgical practices and patient outcomes is integral to the provision of quality gynaecological care. An audit of surgical complications can provide important information needed for an assessment of current surgical practices and outcomes. The aim of the study was to describe the cohort of patients having gynaecological surgical procedures at Tygerberg Hospital, their complication rates and identify associated risk factors.

### **Method**

We conducted a retrospective review of patients, 18 years and older, having emergency and elective gynaecological surgical procedures between 01 January 2019 and 31 December 2019. Nine hundred and seventy patients were included. We summarised categorical data as counts and percentages. We performed bivariate and multivariate logistical regression to assess clinical and surgical factors associated with complications. We reported odds ratios as a measure of association with the corresponding 95% confidence interval. Statistical significance was set at p-value <0.1 and p-value < 0.05 in the bivariate and multivariate analysis, respectively.

### **Results**

Overweight and obese patients accounted for 60% of patients. The most common indications for surgical intervention were early pregnancy complications (22.2%), benign gynaecological conditions (23.3%) and gynaecological malignancy (19.2%). Total abdominal hysterectomy was the single most common procedure performed and accounted for 23.7% of surgical procedures. Intra-operative or post-operative complications occurred in 12.7% of patients, while 1.2% sustained both intra-operative and post-operative complications. The most common complications were infection-related (7.5%) and bowel injury (1.8%). Oncological surgery did not increase the likelihood of complications compared to non-oncological surgery (OR 1.14; CI 0.66-1.97 p-value 0.63). Intra-operative blood loss of more than 500ml was associated with an increase in complications.

### **Conclusion**

The provision of quality gynaecological care requires information on gynaecological surgical practices and patient outcomes. These outcomes should be comparable to both national and international standards. The rates of surgical complications at our facility appear to be higher than local and international studies, with our main contributors being infective-related complications and bowel injuries. The use of an extended course of prophylactic antibiotics could be considered, as well as auditing infection control measures. Those at a higher risk of bowel injury should be identified pre-operatively and the surgery approached with care.

## **Introduction**

Information about current gynaecological surgical practices and patient outcomes is integral to the provision of quality gynaecological care. An audit of surgical complications can provide important information needed for an assessment of current surgical practices and outcomes (25). This information can be utilised for surgical skill development, the provision of information to patients and ultimately improve health care. Surgical complications have been shown to increase the cost burden on a health system and decrease the quality of life of patients (2). Although studies investigating the surgical outcomes have been conducted, these studies either focused on the outcomes of all surgical domains (2–4) or specific procedures and outcomes.

The reported complication rate of gynaecological surgery ranges between 7 and 10% (2,3) The identification of risk factors associated with complications could assist with increased peri-operative surveillance of high risk patients and facilitate in the prevention and/or early detection of complications. In addition to the aforementioned factors, the provision of appropriate peri-operative care aims to decrease the morbidity associated with surgical complications. The data for South African hospitals is limited. In this study, we aimed to describe a cohort of patients having gynaecological surgical procedures, their complications and identify potential risk factors.

## **Methods**

### **Study design**

We conducted a retrospective audit of all women, eighteen years and older, who had emergency or elective gynaecological surgical procedures at Tygerberg Hospital, Western Cape, South Africa between 01 January 2019 and 31 December 2019.

### **Study setting**

Tygerberg Hospital (TBH) is one of the teaching hospitals in the Western Cape and is affiliated with Stellenbosch University. It serves the Eastern Sub-district of the Cape Metropole and serves a heterogeneous population of low- to middle-income status. TBH receives referrals from level one and two health care facilities reaching as far as George, Paarl and Worcester. Medical practitioners employed in the Gynaecology Department include interns, medical officers, registrars, and registered specialists. The service is run on a 24-hour basis, which

includes access to theatre and intensive care units (ICUs). The service includes elective and emergency surgery in general gynaecology and subspecialties such as reproductive medicine, gynaecological oncology and urogynaecology.

### **Study population**

We included female patients, eighteen years or older, who presented to Tygerberg Hospital for elective or emergency gynaecological surgery during the stipulated period. To be included, the patient must have had an anaesthetic administered by an anaesthetist and be admitted for at least one night. We excluded all outpatient surgical procedures and primary obstetric procedures. Obstetric patients requiring gynaecological surgical intervention more than seven days after delivery were included.

### **Data collection**

All theatre registers were reviewed to identify patients to be included. The folder numbers and patient names were used to obtain the patient records from the Electronic Content Management (ECM) at TBH. These records were reviewed for study eligibility and included patients were allocated individual study numbers to ensure their anonymity. The desired demographic and clinical data, and details regarding the surgery, hospital stay, and any readmission due to a complication within six weeks of the surgery, were extracted into a pre-designed data dictionary on RedCap.

### **Data analysis**

Statistical analysis was performed using Stata version 17 (College Station, Texas 77845 USA). Numerical data was summarised as means (standard deviation, SD). We summarised categorical data as counts and percentages. We performed bivariate and multivariate logistical regression to assess clinical and surgical factors associated with complications. We reported odds ratios as a measure of association with the corresponding 95% confidence interval. Statistical significance was set at p-value <0.1 and p-value < 0.05 in the bivariate and multivariate analysis, respectively.

### **Ethical considerations**

Ethics approval was obtained from the Human Research Ethics Committee of the Faculty of Medicine and Health Sciences at Stellenbosch University (S19/10/264). We also obtained

approval from hospital management to conduct the study at TBH. The study is registered with The National Health Research Database. We were granted a waiver of informed consent.

## Results

A total of 1068 patients were identified between 01 January 2019 and 31 December 2019. Nine hundred and seventy (n=970) met the inclusion criteria. The mean age of the cohort was 41 years (range 18-83; SD 14.866).

Table 1 summarises the clinical characteristics of the cohort. A large percentage of patients were either overweight (n=172; 17.7%) or morbidly obese (n=414; 42.7%). Most of the patients were non-smokers (n=698, 72%). Three hundred and two patients had one co-morbidity (31.1%). Hypertension was the most common comorbidity (n=303; 31.2%), followed by human immunodeficiency virus infection (n=145; 14.9%) and diabetes mellitus (n=103; 10.6%). About a fifth of patients had more than one co-morbidity (n=224; 23.1%).

Approximately a fifth of patients required surgical intervention for early pregnancy complications (n=215; 22.5%) with half of this group having ectopic pregnancies (11.3%). A similar proportion of patients had surgery for benign gynaecological conditions (n=226; 23.3%), the most common being leiomyomas (n=83; 8.6%). One hundred and eighty six patients had surgery for gynaecological malignancies and the most common malignancies included endometrial cancer (n=52; 5.4%), ovarian cancer (n=46; 4.7%) and cervical cancer (n=45, 4.6%) Other indications for surgery included sepsis related conditions (n=70, 7.2%), infertility (n=65, 6.7%) and pelvic organ prolapse (n=57, 5.9%).

**Table 1: Clinical characteristics of patients having gynaecological surgery(n= 970)**

Variable	Number of patients (%)
<b>BMI</b>	
<18	26(2.7)
18-25	322(33.2)
>25	586(60.4)
No BMI recorded	36(3.7)
<b>Smoking</b>	
Yes	248(25.6)
No	698(72)
Smoking status unknown	24(2.4)
<b>Comorbidities</b>	
HIV	145(14.9)
Cardiovascular disease	358(36.9)
Pulmonary conditions	75(7.7)
Thromboembolic disease	12(1.2)
Endocrine disorders	126(12.9)
Other co-morbidities	132(13.6)
More than 1 co-morbidity	224(23.1)

**Abbreviations:** BMI- body mass index, HIV- human immunodeficiency virus

The surgical and anaesthetic characteristics of the patients are summarised in Table 2. Almost half of the patients had previous abdominal surgery (n=411, 45.5%). About two-thirds of the patients were classified as American Society of Anaesthesiologist (ASA) 2 (n=624; 64.3%). Six hundred and seventy seven patients (69.8%) had elective surgery. Open surgery was the most common surgical approach (n=703, 72.4%) and the primary surgeon was a specialist in more than half of the cases (58.2%). Total abdominal hysterectomies accounted for 230 (23.7%) of all surgical procedures performed. This was closely followed by salpingectomies or salpingostomies (n=141, 14.5%) for either ectopic pregnancies or fertility purposes. A total of 138 (14.2%) patients had an estimated blood loss of more than 500ml.

**Table 2: Surgical and anaesthetic characteristics patients having gynaecological surgery(n=970)**

<b>Variable</b>	<b>Number of patients(%)</b>
<b>Previous abdominal surgery</b>	
Yes	411(45.5)
No	551(56.8)
Unknown	8(0.8)
<b>ASA</b>	
1	210(21.6)
2	624(64.3)
3	105(10.8)
4	2(0.2)
No ASA status	29(3.0)
<b>Urgency of surgery</b>	
Elective	677(69.8)
Emergency	293(30.2)
<b>Duration of surgery</b>	
<30 minutes	139(14.3)
30 minutes-2 hours	507(52.3)
>2 hours	307(31.6)
No duration noted	17(1.8)
<b>Surgical approach</b>	
Open	703(72.4)
Laparoscopic	264(27.2)
Laparoscopic assisted	3(0.3)
<b>Primary surgeon</b>	
Specialist	565(58.2)
Registrar	388(40)
Intern	2(0.2)
Primary surgeon not noted	15(1.5)
<b>Estimated blood loss</b>	
<500ml	814(83.9)
500-1000ml	89(9.2)
>1000ml	49(5.0)
No recorded EBL	18(1.9)

**Abbreviations:** ASA- American Society of Anaesthesiology, EBL- Estimated blood loss,

During the study period, 123 (12.7%) surgical procedures were complicated by either intra-operative or post-operative complications and a further 12 patients (1.2%) had both intra-operative and post-operative complications (Table 3). Bowel injuries were the most common intra-operative complications and occurred in 17 surgical procedures (1.8%). Three patients sustained multiple intra-operative complications - two of which were bowel- and urinary tract injuries and one bladder injury and uterine perforation. Infective complications were the most common post-operative complications, occurring in 73 patients (7.5%). This was closely followed by medical complications (n=13; 1.3%) and post-operative haemorrhage (n=10;

1.0%). Eleven patients (1.1%) sustained multiple post-operative complications. Two (0.2%) patients demised post-operatively.

**Table 3: Intra-operative and post-operative complications(n=177)**

<b>Complications</b>	<b>Number of occurrences(%)</b>
<b><u>Intra-operative complications</u></b>	
<b>Urinary tract injury</b>	<b>12(1.2)</b>
Bladder	7(0.7)
Ureteric	3(0.3)
Urethral	2(0.3)
<b>Bowel injury</b>	<b>17(1.8)</b>
<b>Uterine perforation</b>	<b>3(0.3)</b>
<b>Medical conditions</b>	<b>1(0.1)</b>
Acute coronary syndrome	1(0.1)
<b>Multiple intra-operative complications</b>	<b>3(0.3)</b>
<b><u>Post-operative complications</u></b>	
<b>Infectious complications</b>	<b>73(7.5)</b>
Blood stream infection	3(0.3)
Deep surgical site sepsis	21(2.2)
Superficial wound sepsis	37(3.8)
Urinary tract infections	12(1.2)
<b>Haemorrhage</b>	<b>10(1.0)</b>
Acute post-operative bleed	5(0.5)
Wound haematoma	2(0.2)
Vault haematoma	3(0.3)
<b>Medical conditions</b>	<b>13(1.3)</b>
Pneumonia	5(0.5)
MINS	1(0.1)
Acute urinary retention	2(0.2)
Symptomatic anaemia	1(0.1)
Lateral cutaneous nerve of thigh injury	1(0.1)
Acute kidney injury	2(0.2)
Pulmonary oedema	1(0.1)
<b>Wound dehiscence</b>	<b>6(0.6)</b>
<b>Bowel related</b>	<b>7(0.7)</b>
Ileus	5(0.5)
Bowel obstruction	2(0.2)
<b>Vesico-vaginal fistula</b>	<b>2(0.2)</b>
<b>Thrombo-embolic events</b>	<b>6(0.6)</b>
Pulmonary emboli	6(0.6)
<b>Multiple post-operative complications</b>	<b>12(1.2)</b>
<b><u>Intraoperative and post-operative complications</u></b>	<b>12(1.2)</b>

Abbreviations: MINS- myocardial injury after non-cardiac surgery

To assess the association between certain clinical and surgical characteristics and complications, a bivariate and multivariate analysis was conducted. The bivariate analysis as described in Table 4 showed that having more than one co-morbidity, smoking, morbid obesity, previous abdominal surgery and an ASA classification of 2 or more had a higher likelihood of complications. However, after a multivariate analysis, only an ASA classification of 3 or more and previous abdominal surgery was associated with a higher likelihood of complications.

Laparoscopic surgery was associated with fewer complications compared to open surgery (OR 0.39, CI 0.22-0.72; p-value 0.002). Surgery performed by registrars as the primary surgeon, compared to specialists were less likely to have complications (OR 0.43, CI 0.21-0.89; p-value 0.02). Women having emergency surgery were less likely to experience complications compared to elective surgery (OR 0.16, CI 0.08-0.33; p-value <0.001). Oncological surgery did not increase the likelihood of complications compared to non-oncological surgery (OR 1.14; CI 0.66-1.97 p-value 0.63). Intra-operative blood loss of more than 500ml was associated with more complications.

**Table 4: Association between clinical and surgical characteristics and complications**

<b><u>Risk factors</u></b>	<b><u>Crude OR</u></b>	<b><u>p-value</u></b>	<b><u>95% CI</u></b>	<b><u>Adjusted OR</u></b>	<b><u>p-value</u></b>	<b><u>95% CI</u></b>
<b>&gt;1 co-morbidity</b>	2.37	<0.001	1.59-3.54	1.30	0.287	0.80-2.12
<b>Smoking</b>	1.47	0.07	0.97-2.22	1.09	0.72	0.69-1.70
<b>BMI</b>						
<18	0.91	0.02	0.57-1.39	1.32	0.06	0.96-6.96
26-30	1.03	0.93	0.59-1.77	1.58	0.07	0.97-2.57
>30	2.95	0.02	1.21-7.22	2.58	0.06	0.74-2.34
<b>Previous abdominal surgery</b>	1.48	0.04	1.01-2.17	1.59	0.03	1.04-2.43
<b>ASA</b>						
2	1.94	0.03	1.07-3.50	1.49	0.21	0.79-2.80
3	5.43	<0.001	2.73-10.79	2.88	0.01	1.27-6.50
<b>Laparoscopic surgery</b>	0.18	<0.001	0.14-0.22	0.39	0.002	0.22-0.72
<b>Primary surgeon</b>						
Specialist	0.53	0.04	0.29-0.96	0.71	0.34	0.36-1.43
Registrar	0.37	<0.001	0.21-0.65	0.43	0.02	0.21-0.89
<b>Urgency of surgery</b>						
Elective	0.57	0.02	0.36-0.91	0.78	0.46	0.41-1.51
Emergency	0.16	<0.001	0.13-0.20	0.16	<0.001	0.08-0.33
<b>Oncological surgery</b>	2.77	<0.001	1.83-4.17	1.14	0.63	0.66-1.97
<b>Estimated blood loss</b>						
500-1000ml	2.65	<0.001	1.55-4.54	2.09	0.01	1.16-3.76
>1000ml	3.10	0.01	1.58-6.06	2.18	0.04	1.04-4.56

**Abbreviations:** ASA- American Association of Anaesthesiology, BMI- body mass index, CI- confidence interval, OR- odds ratio

Table 5 demonstrates the relationship between two well-known infective risk factors and sepsis. HIV and diabetes mellitus both increased the likelihood of complications but this finding was not statistically significant in diabetic patients.

**Table 5: Bivariate analysis between co-morbidities and septic complications**

<b><u>Co-morbidity</u></b>	<b><u>Crude OR</u></b>	<b><u>p-value</u></b>	<b><u>95% CI</u></b>
HIV	2.26	0.008	1.23-4.12
Diabetes mellitus	1.56	0.24	0.75-3.28

**Abbreviations:** HIV- human immunodeficiency virus, CI- confidence interval, OR- odds ratio

The association between an elevated body mass index and wound complications are summarised in table 6. An elevated body mass index is associated with a 60% less likelihood of wound dehiscence and a 2 fold increase in superficial wound sepsis. Both these findings were however not statistically significant.

**Table 6: Bivariate analysis between an elevated BMI and wound complications**

<b>Body mass index &gt; 25</b>	<b>Crude OR</b>	<b>p-value</b>	<b>95% CI</b>
Wound dehiscence	0.47	0.265	0.13-1.77
Superficial surgical site sepsis	1.89	0.121	0.84-4.25

Abbreviations: BMI- body mass index, CI- confidence interval, OR- odds ratio

## Discussion

Surgical complications are known to increase the health burden in terms of cost and quality of life(2). The aim of this study was to describe the cohort of patients, their complication rates and the associations between various characteristics and complications in patients having gynaecological surgery at Tygerberg Hospital.

Internationally, the surgical complication rate across all surgical disciplines was reported to be as high as 20% (2). The ISOS reported that gynaecological surgery had a complication rate of 9.8%, with no difference between high- and middle- or low-income countries. Low- and middle-income countries had a higher mortality rate (3.3%) following complications than high-income countries (2.3%) (2). This finding was supported by the ASOS, where it was found that gynaecological surgery in African countries had a complication rate of about 8% and a mortality rate of 2.1% (4) Our study found a complication rate of 13.9%, which is significantly higher than the international figures. In our study, infective complications were the most common contributors to the overall complication rate and this was consistent with findings of ISOS and ASOS. Interestingly, our study found a significantly lower mortality rate of 0.2%. It is difficult to compare the numbers as the definitions of complications used in our study differed from the ASOS and ISOS and the study designs differed. ISOS only looked at elective surgery in high-, middle- and low-income countries. The inclusion criteria for ASOS was similar to our study. Nonetheless, a complication rate that is significantly higher than international standards is of clinical significance and should prompt further evaluation.

Intra-operatively, 14% of patients had an estimated blood loss of more than 500ml and this was associated with a 2 fold increase in complications. It is known that blood loss above 400ml at hysterectomies for benign conditions is associated with prolonged hospital stay, increased associated complications and higher re-operation rates (12). Despite the common use of blood products, blood transfusions are expensive and may be associated with their own set of complications (9,10). Estimated blood loss is subjective and not easily standardised. To decrease the morbidity associated with significant blood loss and/or blood transfusions, it would be important to optimise pre-operative haemoglobin and use surgical approaches to minimise blood loss.

Visceral injuries were the most common intra-operative complications. The rate of urinary tract injuries in our study was similar to previous studies but there were more bowel injuries. We found that 1.8% of patients sustained a bowel injury, which is almost three times higher than the quoted rate in the literature of 0.3-0.5% (15). Bowel injury, particularly when the diagnosis is delayed, is associated with significant post-operative morbidity and a mortality rate of 3.4% (15). The majority of bowel injuries are to small bowel (75%) with well-known risk factors including previous abdominal surgery, pelvic infection and extensive adhesions (15). Almost half of our study population had previous abdominal surgery and we found a 50% higher likelihood of complications in this group. However, we did not investigate the correlation between previous abdominal surgery and bowel injury alone, nor did we differentiate between large and small bowel injury. Prevention of visceral injury may not always be possible but the recognition of risk factors should prompt a surgical approach with increased care to mitigate this risk. Additionally, these patients should have increased peri-operative surveillance to identify delayed manifestation of such injuries which would decrease the delay in diagnosis and its associated morbidity and mortality.

Infective complications were the most common and almost 80% of these were due to surgical site infection. Two known risk factors were explored, namely co-existing HIV and diabetes mellitus, both of which are immune suppressive conditions that are associated with sepsis (18,26). HIV, particularly those with lower CD4 counts, tend to have higher rates of surgical site sepsis (18). Interestingly, the proportion of HIV infected individuals was higher in our study than ASOS (14.9% vs 11%). The relationship between infective complications and HIV infection was not explored by the authors of ASOS but our study found that individuals with HIV infection were more likely to have infective complications. An increase of about 50% in infective complications in those with diabetes mellitus, despite not being statistically significant, implies that both diabetes and HIV should be regarded as risk factors requiring ongoing surveillance for infective complications.

Thromboembolic events are a leading cause of death in the developed world (27). A systematic review in 2011 by Rahn et al found that 0-2% of surgical procedures for benign gynaecological procedures were complicated by venous thromboembolism (23). Other risk factors like surgery for gynaecological malignancy and being elderly significantly increased the rate of venous thromboembolism (23). Our study found that 0.6% of patients had thromboembolic events following gynaecological surgical procedures. This is consistent with the findings by Rahn et al but our study did not investigate the association between age or gynaecological malignancy and thromboembolic events.

Two patients demised post-operatively. The first patient had complicated oncologic surgery for ovarian cancer with severe intra-operative haemorrhage and a massive blood transfusion. She was admitted to ICU post-operatively, subsequently deteriorated and had a relook laparotomy for possible ongoing haemorrhage, which was excluded. She improved post-operatively but had a sudden cardiac arrest after extubation, with an unsuccessful resuscitation effort. The second patient was morbidly obese with diabetes mellitus and asthma. She developed a pulmonary embolism and puerperal sepsis following a caesarean section. She required a laparotomy due to intra-abdominal sepsis. At laparotomy, multiple bowel injuries and four quadrant sepsis was diagnosed, a hysterectomy and bowel resection was done. Post-operatively she deteriorated with worsening multi-organ dysfunction and demised in ICU.

Interestingly, morbid obesity, once adjusted for other factors, increased the risk of complications by close to 50% but this finding was not statistically significant. An American study reported that an increased body mass index was associated with certain complications like wound dehiscence and wound sepsis but had minimal association with other complications like thromboembolism (20) This finding was consistent with a local study in 2012 where the outcomes of hysterectomies for benign conditions at a public facility was investigated. This study demonstrated a 5-fold increase in wound sepsis in women with an increased body mass index(21). Even though our findings between elevated BMI and wound complications were not statistically significant, a 90% increased risk of wound sepsis in those who were overweight or obese, is of clinical significance. Thus, morbid obesity should still be viewed as a significant risk factor for complications as nearly half of our patient population fall into this category.

Most surgical procedures were performed by specialists but more complications also occurred in this group. This differs from the findings in the VALUE-study where the complication rate in hysterectomies for benign indications had similar outcomes in both the specialist and non-specialist groups (24) The difference we found in this study may be due to specialists performing more challenging surgical procedures. Additionally, a variety of surgical procedures, not only hysterectomies were performed.

Lastly, oncological surgery, which accounted for a fifth of surgical procedures was not associated with a higher likelihood of complications. This is in keeping with the findings of the study by Butt et al (21) Oncological surgery is perceived to be more complex surgery and therefore the findings were surprising.

Our study was not without limitations. It was a retrospective study and was therefore dependent on the record keeping of others and the ability of the investigator to interpret the records. The

six week follow-up period was allocated to allow for delayed complications to be included. There is a possibility that patients may not have followed up at Tygerberg which might have led to under-reporting. A prospective study with similar outcome and the use of a database could be considered in the future.

### **Conclusion**

The delivery of quality gynaecological care requires information about current gynaecological surgical practices and patient outcomes. These outcomes should be comparable to both national and international standards. The rate of surgical complications at our facility appear to be higher than that reported in both national and international studies. Infective complications were the main contributors, which might be attributed a higher rate of HIV infection rate in our study population. The use of an extended course of prophylactic antibiotics in those at risk of infective complications should be explored in the future. Additionally, auditing of intra- and post-operative infection prevention and control measures should also be considered. Those at a higher risk of bowel injury should be identified pre-operatively and the surgery approached with care. Surgical awareness and increased peri-operative surveillance may not eliminate visceral injury but it may decrease the associated morbidity, especially with delayed presentations.

### **Acknowledgements**

We acknowledge Ms Moleen Dzikiti, for assistance with the statistical analysis, and Dr Karis Moxley for the guidance throughout the writing process .

### **Conflict of interest**

The authors declare that they have no competing interests.

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- Quotes should be placed in single quotation marks: i.e. The respondent stated: '...'
- Round brackets (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.

If you wish material to be in a box, simply indicate this in the text. You may use the table format –this is the only exception. Please DO NOT use fill, format lines and so on.

SAJOG is a general specialist obstetrics and gynaecology journal, therefore for articles involving genetics, it is the responsibility of authors to apply the following:

- Please ensure that all genes are in italics, and proteins/enzymes/hormones are not.
- Ensure that all genes are presented in the correct case e.g. TP53 not Tp53.

\*\* NB: Copyeditors cannot be expected to pick up and correct errors wrt the above, although they will raise queries where concerned.

- Define all genes, proteins and related shorthand terms at first mention, e.g. '188del11' can be glossed as 'an 11 bp deletion at nucleotide 188.'
- Use the latest approved gene or protein symbol as appropriate:
  - o Human Gene Mapping Workshop (HGMW): genetic notations and symbols
  - o HUGO Gene Nomenclature Committee: approved gene symbols and nomenclature
  - o OMIM: Online Mendelian Inheritance in Man (MIM) nomenclature and instructions
  - o Bennet et al. Standardized human pedigree nomenclature: Update and assessment of the recommendations of the National Society of Genetic Counselors. *J Genet Counsel* 2008;17:424-433: standard human pedigree nomenclature.

### Preparation notes by article type

#### Research

Guideline word limit: 3 000 words (excluding abstract and bibliography)

Research articles describe the background, methods, results and conclusions of an original research study. The article should contain the following sections: introduction, methods, results, discussion and conclusion, and should include a structured abstract (see below). The introduction should be concise – no more than three paragraphs – on the background to the research question, and must include references to other relevant published studies that clearly lay out the rationale for conducting the study. Some common reasons for conducting a study are: to fill a gap in the literature, a logical extension of previous work, or to answer an important question. If other papers related to the same study have been published previously, please make sure to refer to them specifically. Describe the study methods in as much detail as possible so that others would be able to replicate the study should they need to. Where appropriate, sample size calculations should be included to demonstrate that the study is not underpowered. Results should describe the study sample as well as the findings from the study itself, but all interpretation of findings must be kept in the discussion section. The conclusion should briefly summarise the main message of the paper and provide recommendations for further study.

- May include up to 3 illustrations or tables.
- A max of 20 - 25 references

#### Structured abstract

- This should be no more than 250 words, with the following recommended headings:
  - o Background: why the study is being done and how it relates to other published work.
  - o Objectives: what the study intends to find out
  - o Methods: must include study design, number of participants, description of the research tools/instruments, any specific analyses that were done on the data.
  - o Results: first sentence must be brief population and sample description; outline the results according to the methods described. Primary outcomes must be described first, even if they are not the most significant findings of the study.
  - o Conclusion: must be supported by the data, include recommendations for further study/actions.
    - Please ensure that the structured abstract is complete, accurate and clear and has been approved by all authors. It should be able to be intelligible to the reader without referral to the main body of the article.
    - Do not include any references in the abstracts.

Here is an example of a good abstract.

#### *Scientific letters/short reports*

These are shorter length, scholarly research articles of no more than 1500 words, and include case reports.

Guideline word limit: 1 500 words

- Abstract: Structured, of about 150 words, with the following recommended headings: Background, Objectives, Methods, Results, and Conclusion.
- May include only one illustration or table
- A maximum of 8 references

#### *Editorials*

Guideline word limit: 1 000 words

These opinion or comment articles are usually commissioned but we are happy to consider and peer review unsolicited editorials. Editorials should be accessible and interesting to readers without specialist knowledge of the subject under discussion and should have an element of topicality (why is a comment on this issue relevant now?) There should be a clear message to the piece, supported by evidence. Please make clear the type of evidence that supports each key statement, e.g.:

- expert opinion
- personal clinical experience
- observational studies
- trials
- systematic reviews.

#### *Review articles*

Review articles should always be discussed with the Editor prior to submission.

Guideline word limit: 4 000 words

These are welcome, but should be either commissioned or discussed with the Editor before submission. A review article should provide a clear, up-to-date account of the topic and be aimed at non-specialist hospital doctors and general practitioners. They should be aligned to practice in South and/or sub-Saharan Africa and not a précis of reviews published in the international literature

Please ensure that your article includes:

- Abstract: unstructured, of about 100-150 words, explaining the review and why it is important
- Methods: Outline the sources and selection methods, including search strategy and keywords used for identifying references from online bibliographic databases. Discuss the quality of evidence.
- When writing: clarify the evidence you used for key statements and the strength of the evidence. Do not present statements or opinions without such evidence, or if you have to, say that there is little or no evidence and that this is opinion. Avoid specialist jargon and abbreviations, and provide advice specific to southern Africa.
- Personal details: Please supply your qualifications, position and affiliations and MP number (used for CPD points); address, telephone number and fax number, and your e-mail address; and a short personal profile (50 words) and a few words about your current fields of interest.

#### *Correspondence (Letters to the Editor)*

Guideline word limit: 400 words

Letters to the editor should relate either to a paper or article published by the SAJOG or to a topical issue of particular relevance to the journal's readership

- May include only one illustration or table
- Must include a correspondence address.

#### *Obituaries*

Guideline word limit: 400 words

Should be offered within the first year of the practitioner's death, and may be accompanied by a photograph.

#### **Illustrations/photos/scans**

- If illustrations submitted have been published elsewhere, the author(s) should provide evidence of consent to republication obtained from the copyright holder.
- Figures must be numbered in Arabic numerals and referred to in the text e.g. '(Fig. 1)'.
- Each figure must have a caption/legend: Fig. 1. Description (any abbreviations in full).
- All images must be of high enough resolution/quality for print.
- All illustrations (graphs, diagrams, charts, etc.) must be in PDF form.
- Ensure all graph axes are labelled appropriately, with a heading/description and units (as necessary) indicated. Do not include decimal places if not necessary e.g. 0; 1.0; 2.0; 3.0; 4.0 etc.
- Each image must be attached individually as a 'supplementary file' upon submission (not solely embedded in the accompanying manuscript) and named Fig. 1, Fig. 2, etc.

#### **Tables**

- Tables should be constructed carefully and simply for intelligible data representation. Unnecessarily complicated tables are strongly discouraged.
- Embed/include each table in the manuscript Word file - do not provide separately as supplementary files.
- Number each table in Arabic numerals (Table 1, Table 2, etc.) consecutively as they are referred to in the text.
- Tables must be cell-based (i.e. not constructed with text boxes or tabs) and editable.
- Ensure each table has a concise title and column headings, and include units where necessary.
- Footnotes must be indicated with consecutive use of the following symbols: \* † ‡ § ¶ || then \*\* †† ‡‡ etc.

Do not: Use [Enter] within a row to make 'new rows':

Rather:

Each row of data must have its own proper row:

Do not: use separate columns for n and %:

Rather:

Combine into one column, n (%):

Do not: have overlapping categories, e.g.:

Rather:

Use <> symbols or numbers that don't overlap:

#### **References**

NB: Only complete, correctly formatted reference lists in Vancouver style will be accepted. If reference manager software is used, the reference list and citations in text are to be unformatted to plain text before submitting..

- Authors must verify references from original sources.
- Citations should be inserted in the text as superscript numbers between square brackets, e.g. These regulations are endorsed by the World Health Organization,[2] and others.[3,4-6]
- All references should be listed at the end of the article in numerical order of appearance in the Vancouver style (not alphabetical order).
- Approved abbreviations of journal titles must be used; see the List of

Journals in Index Medicus.

- Names and initials of all authors should be given; if there are more than six authors, the first three names should be given followed by et al.
- Volume and issue numbers should be given.
- First and last page, in full, should be given e.g.: 1215-1217 not 1215-17.
- Wherever possible, references must be accompanied by a digital object identifier (DOI) link). Authors are encouraged to use the DOI lookup service offered by CrossRef:
  - o On the Crossref homepage, paste the article title into the 'Metadata search' box.
  - o Look for the correct, matching article in the list of results.
  - o Click Actions > Cite
  - o Alongside 'url =' copy the URL between { }.
  - o Provide as follows, e.g.: <https://doi.org/10.7196/07294.937.98x>

*Some examples:*

- Journal references: Price NC, Jacobs NN, Roberts DA, et al. Importance of asking about glaucoma. *Stat Med* 1998;289(1):350-355. <http://dx.doi.org/10.1000/hgjr.182>
- Book references: Jeffcoate N. *Principles of Gynaecology*. 4th ed. London: Butterworth, 1975:96-101.
- Chapter/section in a book: Weinstein L, Swartz MN. Pathogenic Properties of Invading Microorganisms. In: Sodeman WA, Sodeman WA, eds. *Pathologic Physiology: Mechanisms of Disease*. Philadelphia: WB Saunders, 1974:457-472.
- Internet references: World Health Organization. *The World Health Report 2002 - Reducing Risks, Promoting Healthy Life*. Geneva: WHO, 2002. <http://www.who.int/whr/2002> (accessed 16 January 2010).
- Legal references
  - Government Gazettes:
    - National Department of Health, South Africa. National Policy for Health Act, 1990 (Act No. 116 of 1990). Free primary health care services. *Government Gazette No. 17507:1514*. 1996. In this example, 17507 is the Gazette Number. This is followed by :1514 - this is the notice number in this Gazette.
    - Provincial Gazettes:
      - Gauteng Province, South Africa; Department of Agriculture, Conservation, Environment and Land Affairs. Publication of the Gauteng health care waste management draft regulations. *Gauteng Provincial Gazette No. 373:3003*, 2003.
    - Acts:
      - South Africa. National Health Act No. 61 of 2003.
    - Regulations to an Act:
      - South Africa. National Health Act of 2003. Regulations: Rendering of clinical forensic medicine services. *Government Gazette No. 35099*, 2012. (Published under Government Notice R176).
    - Bills:
      - South Africa. Traditional Health Practitioners Bill, No. B66B-2003, 2006.
    - Green/white papers:
      - South Africa. Department of Health Green Paper: National Health Insurance in South Africa. 2011.
    - Case law:
      - Rex v Jopp and Another 1949 (4) SA 11 (N)
      - Rex v Jopp and Another: Name of the parties concerned
      - 1949: Date of decision (or when the case was heard)
      - (4): Volume number
      - SA: SA Law Reports
      - 11: Page or section number
      - (N): In this case Natal - where the case was heard. Similarly, (C) would

indicate Cape, (G) Gauteng, and so on.

NOTE: no . after the v

- Other references (e.g. reports) should follow the same format: Author(s). Title. Publisher place: Publisher name, year; pages.
- Cited manuscripts that have been accepted but not yet published can be included as references followed by '(in press)'.
- Unpublished observations and personal communications in the text must not appear in the reference list. The full name of the source person must be provided for personal communications e.g. '(Prof. Michael Jones, personal communication)'.

#### **From submission to acceptance**

##### *Submission and peer-review*

To submit an article:

- Please ensure that you have prepared your manuscript in line with the SAJOG requirements.
- All submissions should be submitted via Editorial Manager
- The following are required for your submission to be complete:
  - o Anonymous manuscript (unless otherwise stated)
  - o Author Agreement form
  - o Manuscript
  - o Any supplementary files: figures, datasets, patient consent form, permissions for published images, etc.
- Once the submission has been successfully processed on Editorial Manager, it will undergo a technical check by the Editorial Office before it will be assigned to an editor who will handle the review process. If the author guidelines have not been appropriately followed, the manuscript may be sent back to the author for correcting.

##### *Peer Review Process*

All manuscripts are reviewed initially by the Editor-in-Chief and only those that meet the scientific and editorial standards of the journal, and fit within the aims and scope of the journal, will be sent for external peer review. Each manuscript is reviewed by two reviewers selected on the basis of their expertise in the field. A double blind review process is followed at SAJOG.

Authors are expected to receive feedback from reviewers and an editorial decision within approximately 6 weeks of submission. The time period of the entire review process may vary however depending upon the quality of the manuscript submitted, reviewers' responses and the time taken by the authors to submit the revised manuscript.

Manuscripts from review may be accepted, rejected or returned to the author for revision or resubmission for review. Authors will be directed to submit revised manuscripts within two months of receiving the editor's decision, and are requested to submit a point by point response to the reviewers' comments. Manuscripts which authors are requested to revise and resubmit will be sent for a second round of peer review, often to the original set of reviewers. All final decisions on a manuscript are at the Editor's discretion

##### *Production process*

1. An accepted manuscript is passed to a Managing Editor to assign to a copyeditor (CE).
2. The CE copyedits in Word, working on house style, format, spelling/grammar/punctuation, sense and consistency, and preparation for typesetting.
3. If the CE has an author queries, he/she will contact the corresponding author and send them the copyedited Word doc, asking them to solve the queries by means of track changes or comment boxes.
4. The authors are typically asked to respond within 1-3 days. Any

- comments/changes must be clearly indicated e.g. by means of track changes. Do not work in the original manuscript - work in the copyedited file sent to you and make your changes clear.
5. The CE will finalise the article and then it will be typeset.
  6. Once typeset, the CE will send a PDF of the file to the authors to complete their final check, while simultaneously sending to the 2nd-eye proofreader.
  7. The authors are typically asked to complete their final check and sign-off within 1-2 days. No major additional changes can be accommodated at this point.
  8. The CE implements the authors' and proofreader's mark-ups, finalises the file, and prepares it for the upcoming issue.

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#### Errata and retractions

##### *Errata*

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- Article title and authors
- Description of error and details of where it appears in the published article
- Full detail of proposed correction and rationale

We will investigate the issue and provide feedback. If appropriate, we will correct the web version immediately, and will publish an erratum in the next issue. All investigations will be conducted in accordance with guidelines provided by the Committee on Publication Ethics (COPE).

##### *Retractions*

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- Article title and authors
- Description of reason for withdrawal/retraction.

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Comprehensive feedback will be communicated with the authors with regard to the process. In case where there is any suspected fraud or professional misconduct, we will follow due process as recommended by the Committee on Publication Ethics (COPE), and in liaison with any relevant institutions.

When a retraction is published, it will be linked to the original article.

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Contact the managing editor ([claudian@samedical.org](mailto:claudian@samedical.org)) for information on submitting ad hoc/commissioned supplements, including guidelines, conference/congress abstracts, etc.

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### **Submission Preparation Checklist**

As part of the submission process, authors are required to check off their submission's compliance with all of the following items, and submissions may be returned to authors that do not adhere to these guidelines.

1. Named authors consent to publication and meet the requirements of authorship as set out by the journal.
  2. The submission has not been previously published, nor is it before another journal for consideration.
  3. The text complies with the stylistic and bibliographic requirements in **Author Guidelines**.
  4. The research was approved by a Research Ethics Committee (if applicable)
  5. The authors are aware of the page fee costs associated with their submission. Please see **Author Guidelines** for more information.
- 

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## Appendix B – Ethics approval



UNIVERSITEIT  
STELLENBOSCH  
UNIVERSITY

**Approval Notice**

**New Application**

14/06/2020

**Project ID** :12998

**HREC Reference No:** S19/10/264

**Project Title:** What is the surgical complication rate of patients undergoing gynaecological surgery at Tygerberg Hospital? A retrospective study

Dear Dr Tasneem Gallant

We refer to your response received on 04/06/2020 . Please be advised that your submission was reviewed and **approved** by members of **Health Research Ethics Committee** via **expedited** review procedures on 14/06/2020 .

Please note the following information about your approved research protocol:

**Protocol Approval Date: 14 June 2020**

**Protocol Expiry Date: 13 June 2021**

Please remember to use your Project ID 12998 and Ethics Reference Number S19/10/264 on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

### **After Ethical Review**

Translation of the informed consent document(s) to the language(s) applicable to your study participants should now be submitted to the HREC.

Please note you can submit your progress report through the online ethics application process, available at: Links Application Form Direct Link and the application should be submitted to the HREC before the year has expired. Please see [Forms and Instructions](#) on our HREC website ([www.sun.ac.za/healthresearchethics](http://www.sun.ac.za/healthresearchethics)) for guidance on how to submit a progress report.

The HREC will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.

### **Provincial and City of Cape Town Approval**

Please note that for research at a primary or secondary healthcare facility, permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Please consult the Western Cape Government website for access to the online Health Research Approval Process, see: <https://www.westerncape.gov.za/general-publication/health-research-approval-process>. Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.

For standard HREC forms and instructions, please visit: [Forms and Instructions](#) on our HREC website <https://applyethics.sun.ac.za/ProjectView/Index/12998>

If you have any questions or need further assistance, please contact the HREC office at 021 938 9657.

Yours sincerely,

Mrs. Melody Shana

Coordinator

HREC1

*National Health Research Ethics Council (NHREC) Registration Number:*

*REC-130408-012 (HREC1)•REC-230208-010 (HREC2)*

## Appendix C – RedCap data collection tools

**Confidential** What is the surgical complication rates of patients undergoing gynaecological surgery at Tygerberg Hospital? A retrospective study  
Page 1

## My First Instrument

---

Record ID \_\_\_\_\_

---

Age \_\_\_\_\_

---

BMI 
 < 18  
 18-25  
 26-30  
 >30

---

Smoker? 
 Yes  
 No

---

Co-morbidities 
 HIV  
 Hypertension  
 Congestive cardiac failure  
 COPD  
 Hyperthyroidism  
 Hypothyroidism  
 Non-gynaecological malignancy  
 Diabetes  
 Ischemic heart disease  
 Asthma  
 Previous stroke or TIA  
 Chronic kidney disease  
 Tuberculosis  
 Other

---

If other, state comorbidity \_\_\_\_\_

---

ASA Classification 
 1  
 2  
 3  
 4

---

Starting haemoglobin 
 < 8  
 8-10  
 >10

---

Urgency of surgery 
 Elective  
 Emergency

---

Severity of surgery 
 Major  
 Minor

---

Anaesthetic 
 General  
 Spinal  
 Epidural  
 Local or other regional  
 TIVA  
 sedation

---

23/03/2020 13:46 projectredcap.org 

Confidential

Page 2

Duration of surgery	<input type="radio"/> < 30 minutes <input type="radio"/> 30min- 2 hours <input type="radio"/> >2 hours
Surgical approach	<input type="radio"/> Open <input type="radio"/> Laparoscopic <input type="radio"/> Laparoscopic assisted
Surgery	<input type="radio"/> Abdominal hysterectomy <input type="radio"/> Adhesiolysis <input type="radio"/> Adnexectomy <input type="radio"/> Anterior repair <input type="radio"/> Bilateral Tubal ligation <input type="radio"/> Cauterization of warts <input type="radio"/> Cold knife cone biopsy <input type="radio"/> Cystectomy <input type="radio"/> Cytoreductive surgery <input type="radio"/> Diagnostic laparoscopy <input type="radio"/> Endometriosis excision/ablation <input type="radio"/> Evacuation of uterus <input type="radio"/> Examination under anaesthesia <input type="radio"/> Hysteroscopy <input type="radio"/> Incision and drainage of abscess <input type="radio"/> LeFort procedure <input type="radio"/> Lymnode dissection <input type="radio"/> Manchester Procedure <input type="radio"/> Marsupialization of Bartholin's abscess <input type="radio"/> Myomectomy <input type="radio"/> PID surgery <input type="radio"/> Posterior repair <input type="radio"/> Relook laparotomy <input type="radio"/> Sacrocolpopexy <input type="radio"/> Salpingectomy/salpingostomy <input type="radio"/> Secondary wound closure <input type="radio"/> Secondary perineal tear repair <input type="radio"/> Tension free vaginal tape <input type="radio"/> Vaginal hysterectomy <input type="radio"/> Wide local excision <input type="radio"/> Wound exploration <input type="radio"/> Other
If other, state surgery	_____
Primary surgeon	<input type="radio"/> Consultant <input type="radio"/> Senior registrar(3rd or 4th year) <input type="radio"/> Junior registrar (1st or 2nd year) <input type="radio"/> Senior MO(>3 years) <input type="radio"/> Junior MO(< 3 years) <input type="radio"/> Intern
Estimated blood loss	<input type="radio"/> < 500ml <input type="radio"/> 500ml-1000ml <input type="radio"/> >1000ml
Blood transfusion	<input type="radio"/> Yes <input type="radio"/> No

Confidential

Page 3

---

Blood products received	<input type="radio"/> < 5 units packed cells <input type="radio"/> > 5 units packed cells <input type="radio"/> FFPs FDPs <input type="radio"/> Platelets <input type="radio"/> Cryoprecipitate
Intra-operative complications	<input type="radio"/> Bladder injury <input type="radio"/> Bowel injury <input type="radio"/> Ureteric injury <input type="radio"/> Other
If other, state intra-operative complication	_____
Post-operative complications	<input type="radio"/> Blood stream infection <input type="radio"/> Deep vein thrombosis <input type="radio"/> Deep surgical site sepsis <input type="radio"/> Fistula formation <input type="radio"/> Intra-abdominal collections <input type="radio"/> Pneumonia <input type="radio"/> Post-operative haemorrhage <input type="radio"/> Pulmonary embolism <input type="radio"/> Wound/sheath dehiscence <input type="radio"/> Superficial surgical site sepsis <input type="radio"/> Urinary tract infection <input type="radio"/> Wound hematoma <input type="radio"/> Other
If other, state complication	_____

## Appendix D: Data dictionary

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V
1	Variable / Field Name, "Form Name", "Section Header", "Field Type", "Field Label", "Choices, Calculations, OR Slider Labels", "Field Note", "Text Validation Type OR Show Slider Number", "Text Validation Min", "Text Validation Max", "Identifier?", "Branching Logic (Show field only if...)", "Required Field"																				
2	record_id,my_first_instrument,text,"Record ID",,,,,,,,,,,,,,																				
3	age,my_first_instrument,text,Age,,,,,,,,,,,,,																				
4	bmi,my_first_instrument,radio,BMI,"1, <18   2, 18-25   3, 26-30   4, >30",,,,,,,,,,,,,,																				
5	smoker,my_first_instrument,yesno,Smoker?,"1, Yes																				
6	2, No",,,,,,,,,,,,,,																				
7	comorbidities,my_first_instrument,dropdown,Co-morbidities,"1, HIV   2, Hypertension   3, Congestive cardiac failure   4, COPD   5, Hyperthyroidism   6, Hypothyroidism   7, Non-gynaecological malignancy   8, Diabetes   9, Ischemic heart disease   10, Asthma   11, Previous stroke or TIA																				
8	otyer_comorbidity,my_first_instrument,text,"If other, state comorbidity",,,,,,,,,,,,,,																				
9	asa,my_first_instrument,radio,"ASA Classification",,"1, 1   2, 2   3, 3   4, 4",,,,,,,,,,,,,,																				
10	starting_hb,my_first_instrument,radio,"Starting haemoglobin",,"1, <8   2, 8-10   3, >10",,,,,,,,,,,,,,																				
11	urgency_of_surgery,my_first_instrument,radio,"Urgency of surgery",,"1, Elective   2, Emergency",,,,,,,,,,,,,,																				
12	severity,my_first_instrument,radio,"Severity of surgery",,"1, Major   2, Minor",,,,,,,,,,,,,,																				
13	anaesthetic,my_first_instrument,radio,"Anaesthetic",,"1, General   2, Spinal   3, Epidural   6, Local or other regional   4, TIVA   5, sedation",,,,,,,,,,,,,,																				
14	duration,my_first_instrument,radio,"Duration of surgery",,"1, <30 minutes   2, 30min-2 hours   3, >2 hours",,,,,,,,,,,,,,																				
15	surgical_approach,my_first_instrument,radio,"Surgical approach",,"1, Open   2, Laparoscopic   3, Laparoscopic assisted",,,,,,,,,,,,,,																				
16	surgery,my_first_instrument,dropdown,"Surgery",,"1, Abdominal hysterectomy   2, Adhesiolysis   3, Adnexectomy   4, Anterior repair   5, Bilateral Tubal ligation   6, Cauterization of warts   7, Cold knife cone biopsy   8, Cystectomy   9, Cytoreductive surgery   10, Diagnostic laparoscopy																				
17	other_surgery,my_first_instrument,text,"If other, state surgery",,,,,,,,,,,,,,																				
18	primary_surgeon,my_first_instrument,radio,"Primary surgeon",,"1, Consultant   2, Senior registrar(3rd or 4th year)   3, Junior registrar (1st or 2nd year)   4, Senior MO(>3 years)   5, Junior MO(<3 years)   6, Intern",,,,,,,,,,,,,,																				
19	ebi,my_first_instrument,radio,"Estimated blood loss",,"1, <500ml   2, 500ml-1000ml   3, >1000ml",,,,,,,,,,,,,,																				
20	blood_transfusion,my_first_instrument,yesno,"Blood transfusion",,,,,,,,,,,,,,																				
21	blood_products,my_first_instrument,radio,"Blood products received",,"1, <5 units packed cells   2, >5 units packed cells   6, FFPs FDPs   4, Platelets   5, Cryoprecipitate",,,,,,,,,,,,,,																				
22	intra_op_complications,my_first_instrument,radio,"Intra-operative complications",,"1, Bladder injury   2, Bowel injury   3, Ureteric injury   4, Other",,,,,,,,,,,,,,																				
23	other_intraop,my_first_instrument,text,"If other, state intra-operative complication",,,,,,,,,,,,,,																				
24	postvoop_complications,my_first_instrument,dropdown,"Post-operative complications",,"1, Blood stream infection   2, Deep vein thrombosis   3, Deep surgical site sepsis   4, Fistula formation   5, Intra-abdominal collections   6, Pneumonia   7, Post-operative haemorrhage   8, Pulmonary																				
25	other_complication,my_first_instrument,text,"If other, state complication",,,,,,,,,,,,,,																				
26																					
27																					
28																					
29																					
30																					

**Appendix E: Comprehensive tables****Table 1: Clinical characteristics of patients having gynaecological surgery (n=970)**

<b>Variable</b>	<b>Number of patients (%)</b>
<b>BMI</b>	
<18	26(2.7)
18-25	322(33.2)
>25	586(60.4)
No BMI recorded	36(3.7)
<b>Smoking</b>	
Yes	248(25.6)
No	698(72)
Smoking status unknown	24(2.4)
<b>Comorbidities</b>	
HIV	145(14.9)
Cardiovascular disease	358(36.9)
<i>hypertension</i>	303(31.2)
<i>congestive cardiac failure</i>	9(0.9)
<i>ischaemic heart disease</i>	20(2.1)
<i>previous stroke or TIA</i>	12(1.2)
<i>dysrhythmias</i>	5(0.5)
<i>valve lesions</i>	5(0.5)
<i>peripheral vascular disease</i>	2(0.2)
<i>congenital heart disease</i>	2(0.2)
Pulmonary conditions	75(7.7)
<i>COPD</i>	25(2.6)
<i>asthma</i>	39(4.0)
<i>tuberculosis</i>	9(0.9)
<i>structural lung disease</i>	2(0.2)
Thromboembolic disease	<b>12(1.2)</b>
<i>DVT</i>	5(0.5)
<i>previous DVT</i>	2(0.2)
<i>pulmonary embolism</i>	4(0.4)
<i>thrombophilia</i>	1(0.1)
Endocrine disorders	126(12.9)
<i>diabetes mellitus</i>	103(10.6)
<i>hyperthyroidism</i>	5(0.5)
<i>hypothyroidism</i>	18(1.9)
<u>Other comorbidities</u>	132(13.6)
<u>Nil comorbidities</u>	444(45.8)
<u>More than 1 comorbidity</u>	224(23.1)

<b>Primary gynaecological diagnosis</b>	
Gynaecological oncology	186(19.2)
<i>cervix cancer</i>	45(4.6)
<i>endometrial cancer</i>	52(5.4)
<i>fallopian tube cancer</i>	2(0.2)
<i>Leiomyosarcoma/sarcoma</i>	6(0.6)
<i>malignant melanoma</i>	1(0.1)
<i>ovarian cancer</i>	46(4.7)
<i>vulva cancer</i>	31(3.2)
<i>vaginal cancer</i>	2(2.2)
Early pregnancy complications	215(22.2)
<i>ectopic pregnancy</i>	110(11.3)
<i>miscarriage</i>	86(8.9)
<i>extra-uterine pregnancy</i>	2(0.2)
<i>gestational trophoblastic disease</i>	17(1.7)
Benign gynaecological conditions	226(23.3)
<i>adenomyosis</i>	11(1.1)
<i>abnormal uterine bleeding</i>	53(5.5)
<i>condylomata</i>	7(0.7)
<i>ovarian cysts and complications</i>	65(6.7)
<i>leiomyoma</i>	83(8.6)
<i>pre-malignant conditions</i>	7(0.7)
Sepsis related conditions	70(7.2)
<i>PID</i>	13(1.3)
<i>puerperal sepsis</i>	14(1.4)
<i>wound sepsis</i>	30(3.1)
<i>necrotizing fasciitis</i>	2(0.2)
<i>abscess</i>	11(1.1)
Reproductive medicine and chronic pelvic pain	159(16.4)
<i>endometriosis</i>	56(5.7)
<i>infertility</i>	65(6.7)
<i>chronic pelvic pain</i>	20(2.1)
<i>contraception related procedures</i>	18(1.9)
Urogynaecology	114(11.8)
<i>pelvic organ prolapse</i>	57(5.9)
<i>perineal trauma</i>	8(0.8)
<i>urinary incontinence and recurrent UTIs</i>	38(3.9)
<i>fistulae</i>	11(1.1)

**Abbreviations:** BMI- Body mass index, COPD- chronic obstructive pulmonary disease, DVT- deep vein thrombosis, HIV- human immunodeficiency virus, n-number, PID- pelvic inflammatory disease, TIA- transient ischaemic attack, UTI- urinary tract infection

**Table 2: Surgical and anaesthetic characteristics patients having gynaecological surgery(n=970)**

<b>Variable</b>	<b>Number of patients(%)</b>
<b>Previous abdominal surgery</b>	
yes	411(45.5)
no	551(56.8)
unknown	8(0.8)
<b>ASA</b>	
1	210(21.6)
2	624(64.3)
3	105(10.8)
4	2(0.2)
No ASA status	29(3.0)
<b>Urgency of surgery</b>	
elective	677(69.8)
emergency	293(30.2)
<b>Duration of surgery</b>	
<30 minutes	139(14.3)
30 minutes-2 hours	507(52.3)
>2 hours	307(31.6)
No duration noted	17(1.8)
<b>Surgical approach</b>	
open	703(72.4)
laparoscopic	264(27.2)
laparoscopic assisted	3(0.3)
<b>Primary surgeon</b>	
specialist	565(58.2)
registrar	388(40)
intern	2(0.2)
primary surgeon not noted	15(1.5)
<b>Surgery</b>	
<b>Starting haemoglobin</b>	
<8	70(7.2)
8-10	193(20)
>10	691(71.2)
No starting Hb known	16(1.6)
<b>Surgery</b>	
adnexectomy/cystectomy	55(5.7)
Bricker's or loop colostomy	2(0.2)
cauterization of warts	3(0.3)
cone biopsy	7(0.7)
contraceptive related procedures	17(1.8)
debulking surgery	7(0.7)
diagnostic laparoscopy	30(3.1)
endometriosis surgery	44(4.5)
evacuation of uterus	97(10)
EUA +/- biopsy	12(1.2)
exploratory laparotomy, relook laparotomy, wound debridement +/- secondary closure	61(6.3)

fistula surgery	7(0.7)
hysteroscopy and hysteroscopic related procedures	9(0.9)
I&D of abscess +/-marsupialization	11(1.1)
myomectomy	55(5.7)
ovarian drilling	1(0.1)
perineal repair	9(0.9)
prolapse surgery	40(4.1)
radical hysterectomy +/- pelvic lymph node dissection	17(1.8)
radical vulvectomy or wide local excision +/- lymph node dissection	34(3.5)
Salpingectomy or salpingostomy	141(14.5)
total abdominal hysterectomy +/- bilateral salpingoophorectomy +/- lymph node dissection +/- omentectomy or omental biopsy	230(23.7)
total laparoscopic hysterectomy +/- bilateral salpingoophorectomy +/- lymph node dissection	14(1.4)
trachelectomy or vaginectomy	2(0.2)
urinary incontinence surgery	32(3.3)
vaginal hysterectomy	33(3.4)
<b>Starting haemoglobin</b>	
<8	70(7.2)
8-10	193(20)
>10	691(71.2)
No starting Hb known	16(1.6)
<b>Estimated blood loss</b>	
<500ml	814(83.9)
500-1000ml	89(9.2)
>1000ml	49(5.1)
No recorded EBL	18(1.9)
<b>Blood transfusion</b>	
Yes	171(17.6)
No	799(82.4)
<b>Blood products transfused</b>	
<5 packed cells	159(16.4)
>5 packed cells	11(1.1)
FDPs or FFPs	34(3.5)
cryoprecipitate	5(0.5)
platelets	3(0.3)

**Abbreviations:** ASA- American Society of Anaesthesiology, EBL- Estimated blood loss, EUA- examination under anaesthesia, FDP- Freeze dried plasma, FFP- fresh frozen plasma, Hb- Haemoglobin, I&D- incision and drainage, TAH- Total Abdominal Hysterectomy, TVT- transvaginal tape